BIOMARKER STUDY EVALUATION TEMPLATE

Evaluator's Name:

Date of Evaluation:

Concept/BIQSFP ID Number and Title:

Instructions for BIQSFP Evaluators: You have been asked to provide an evaluation of the biomarker study associated with the attached phase 2 or phase 3 concept. Your responsibilities consist of evaluating the proposed study and completing this form with your written comments by filling out the fields that follow each review criterion.

Please use the applicant's responses within the *BIQSFP Study Packet, including the Checklist and Budget documents,* in completing your evaluation.

After completing this form, please save it to a new file, attach the form to an e-mail message referencing the concept/BIQSFP number, and forward the email to the NCI/EMMES Program Staff responsible for sending this evaluation. Submit your response at least 3 business days preceding the study evaluation conference call, so that all perspectives may be shared, and your written comments viewed by other evaluators of this study. You will likewise be provided access to the written comments of the other evaluators.

Criteria for Review and Prioritization of *Essential Biomarker Studies*

1. **The strength of the preliminary data for feasibility, utility, and performance characteristics**

   Strengths:

   Weaknesses:

2. **The potential of the test to change practice and have high impact on patient care (i.e.; the potential impact of the test itself or the potential change of therapy indicated by the results of the trial)**

   Strengths:

   Weaknesses:

3. **The ability of the test to yield well defined and validated interpretations that will guide decision-making**

   Strengths:

   Weaknesses:

4. **The extent of standardization of the tests as to be transferable to the non-research setting**

   Strengths:

   Weaknesses:

5. **The adequacy of the process for specimen collection and processing including feasibility data**

   Strengths:

   Weaknesses:

6. **A description of potential cost-sharing approaches that can be developed with entities that would eventually commercialize the test**

   Strengths:

   Weaknesses:

7. **Based on the definitions provided and on your evaluation of the study do you consider this test(s) to be ****INTEGRAL*** **or ****INTEGRATED*** **(see * below) to the associated clinical concept and why?**

- ***Integral Studies** - Defined as assays that must be performed in order for the trial to proceed. Integral studies are inherent to the design of the trial from the onset and must be performed in real time for the conduct of the trial. Integral biomarkers require a CLIA-certified lab. Studies that will be conducted in the future on stored specimens are **not** eligible for BIQSFP funding, except if the results are critical to the stated primary or secondary objectives of the trial

- ***Integrated Studies** – Defined as tests that are clearly identified as part of the clinical trial from the outset and are intended to identify or validate assays or markers that are planned for use in future trials. Integrated studies in general should be designed to test a hypothesis, not simply to generate a hypothesis. The number of integrated assays performed should be sufficient to obtain scientifically valid outcomes during the trial and include complete plans for specimen collection, laboratory measurements, proposed cutpoints, and statistical analysis. One example would be predictive biomarker assays that are measured either in vitro or in vivo where the assay result is not used for eligibility, treatment assignment, or treatment management in the current trial.

    - **REAL TIME** INTEGRATED ASSAY? Some integrated studies may require that assays or tests be performed during the trial, for example, biomarker assays that require a fresh tumor biopsy or real time processing of a blood or tissue sample, or imaging tests to measure treatment response.

    - **NON-REAL TIME** INTEGRATED ASSAY? Other integrated studies do not require real time assays/tests or sample collection or processing. Examples of NRT integrated assays/tests include tools to analyze scans collected as part of standard treatment, gene expression studies that correlate with outcome, and PD-L1 assays performed on diagnostic tumor samples where the results are not used for eligibility, treatment assignment, or treatment management.

8. **It is not intended that any priority or particular level of merit be assigned to one of the previous criteria over another. Based on the strength of the information presented and your scientific judgment, is your level of enthusiasm for the study:**

High				**Mild**
1	2	3	4	5

9. **Please comment on the attached Budget and justification. (see #8 on Biomarker Checklist). Provide recommendations if needed.**

It is understood that by agreeing to assist in this evaluation, you have no conflicts of interest with this concept. In addition, all unpublished information, reports, and discussions are strictly confidential.